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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA,

SAN FRANCISCO DIVISION

GUARDANT HEALTH, INC.

Plaintiff and Counterclaim-Defendant,

vs.

NATERA, INC.

Defendant and Counterclaim-Plaintiff.

CASE NO. 3:21-CV-04062-EMC

NATERA'S MOTION FOR JUDGMENT AS A MATTER OF LAW ON GUARDANT'S CLAIMS

NOTICE OF MOTION AND MOTION

TO ALL PARTIES AND THEIR COUNSEL OF RECORD:

PLEASE TAKE NOTICE, before the Honorable Edward M. Chen, Defendant Natera, Inc. ("Natera") moves for judgment as a matter of law on each of Plaintiff's claims under Federal Rule of Civil Procedure 50(a). Natera submits this motion and memorandum in further support of the oral motion made on the record on November 14, 2024. This motion is based on the testimony and evidence admitted during Plaintiff's case-in-chief.

Natera seeks oral argument.

STATEMENT OF RELIEF SOUGHT

Natera seeks judgment as a matter of law on each of Plaintiff's claims.

DATED: November 14, 2024

QUINN EMANUEL URQUHART & SULLIVAN, LLP

By /s/ *Brian C. Cannon*

Attorneys for NATERA, INC., a Delaware corporation, Defendant and Counterclaim Plaintiff

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INTRODUCTION

In 2021, Natera sent doctors two sets of material—an email with attached slides (TX-365 "Evidence Review") and a FedEx package including the White Paper (TX-120) and a performance grid (TX-126). This trial has stripped down Guardant's allegations to the claim that Natera committed false advertising by including—amongst and beside copious other technical material—a comparison of results from two peer-reviewed studies, Reinert (TX-4) and Parikh (TX-1). This comparison is the basis for Guardant's "apples-to-oranges" allegation. There is no dispute the side-by-side tables accurately reproduced data from the two peer-reviewed articles. Dkt. 326 at 13 ("The numbers are not literally false on their face."). The side-by-side comparisons presented at trial do not and cannot lead to liability under the Lanham Act, U.S. Constitution, or California law, whether reviewed on their own or in their full context. Natera is entitled to judgment as a matter of law.

With respect to the Lanham Act, Guardant's trial presentation suffers several fatal failures of proof. ***First***, there is no proof that Natera's accused statements are false or misleading. The accused side-by-side tables within Natera's publications are not statements of fact capable of being proven true or false. Given that there is no dispute regarding the data presented, what is left is whether one set of data is comparable to the other, and that is a matter of opinion. There is no test or experiment to verify whether the studies are comparable or not. Next, no reasonable jury could find that the side-by-side comparisons were false by necessary implication. The "necessary implication" prong of literal falsity requires that, "considering the advertisement in its entirety, the only reasonable interpretation of the statement is that it is untrue." But Guardant's own evidence has shown there are many reasonable interpretations of the side-by-side table. Guardant itself offered a side-by-side comparison of the Reinert and Parikh data when it applied for Medicare coverage. TX-585; TX-89 at 25. And Guardant compared the data internally. Indeed, the Parikh paper (with Guardant co-authors) invites on its face comparison to Reinert. TX-1 at 2, 4, 5 ("Based on methods employed by Reinert" et al.). Comparability is established by Guardant's own evidence.

Furthermore, even if not literally false, the comparisons were not "misleading" as required. There is no evidence that the side-by-side table, amongst all the other technical information and oncologists' own knowledge, caused any actual deception, and certainly none among a substantial

segment of doctors. There is nothing in the record to support a jury finding on this element.

Second, there was no evidence that the accused statements actually deceived or had the tendency to deceive a substantial segment of the intended audience—highly educated oncologists who review data and studies. No oncologists testified they were deceived. Guardant's expert statistician expert is not an oncologist and spoke to none. And the survey asked the wrong question, only addressing two metrics from one document.

Third, Guardant failed to provide sufficient evidence that any alleged deception was material in that it is likely to influence a purchasing decision. Guardant's survey expert conceded his survey did not test for purchasing decisions, and Guardant offered no other proof for this element.

Fourth, Guardant has failed to prove its request for damages. Guardant's expert explained that his disgorgement theory was a "penalty" for Natera, which is the wrong standard. The damages must be "as a result" of the alleged false statement, which Guardant failed to establish. And the corrective advertising calculation with an arbitrary multiplier is pure speculation.

Importantly, trial has shown that First Amendment principles preclude Guardant's claims. Under *ONY, Inc. v. Cornerstone Therapeutics, Inc.*, 720 F.3d 490 (2d Cir. 2013)—which this Court has ruled applies in this action—free speech principles inform the application of the Lanham Act, and those principles preclude liability for reliance on peer-reviewed studies. *Id.* at 497. Just as *ONY* dismissed Lanham Act claims deriving from promotional materials setting forth the results of peer-reviewed studies, so too should this Court dismiss Guardant's claims which, now, are reduced to simply a table comparing the results of peer-reviewed studies.

Separately, First Amendment precedent provides that Natera's accused publications, the Evidence Review and the White Paper are fully protected as speech on matters of public concern. They are not traditional advertisements for a product with an offer of sale. The White Paper is a highly technical publication about the emerging technology of testing for circulating tumor DNA (ctDNA) to assess the risk of recurrence of colorectal cancer, a major health issue in the United States. Guardant's own witness (Odegaard) conceded that publications like the White Paper are used to educate doctors. Thus, the accused publications include not just the side-by-side comparisons of two peer-reviewed studies, but also significant sections of protected speech not

accused in any way of being false or misleading. In such situations, when the commercial aspects of the speech are "inextricably intertwined" with protected speech, "the publication sheds its commercial character and becomes fully protected speech." *Dex Media West, Inc. v. City of Seattle*, 696 F.3d 952, 958 (9th Cir. 2012). Because Natera's accused publications are fully protected speech, and the accused comparisons are part of those publications, it was incumbent on Guardant to prove liability under First Amendment standards by clear and convincing evidence, including actual malice as to the truth of the publications—which it has not and cannot do.

Natera is also entitled to judgment as a matter of law because Guardant has failed to offer evidence to satisfy its burden of proving unfair competition under California common law. Guardant cannot simply point to its Lanham Act allegations to support its California claim. California courts require certain elements to sustain the cause of action, which Guardant has failed to meet. Finally, Guardant has failed to meet its burden for willfulness or punitive damages.

BACKGROUND

Colorectal cancer ("CRC") is the second leading cause of cancer death in the United States for men and women combined. Dkt. 501 at 4 (Undisputed Facts in Pretrial Conference Order); Dkt. 326 at 2. "Even after treatment, some CRC patients still have a small number of CRC cells remaining in the body that can later multiply and cause recurrence of the disease—termed molecular/minimal residual disease ('MRD')." Dkt. 326 at 2; Tr. 710:25-7:11:6.

Natera's Signatera (commercially launched for clinical use in May 2019) and Guardant's Reveal (commercially launched for clinical use in February 2021) are used to detect the recurrence of CRC. Dkt. 501 at 4. "The Signatera assay requires initial genomic profiling of tumor tissue taken from the patient, which is then used to identify a panel of tumor-derived mutations specific to that patient (termed 'tumor-informed')." Dkt. 326 at 4; Tr. 284:14-23 (Odegaard). The Reveal assay is plasma-only and detects MRD in post-operative CRC patients without a prior sampling of tumor tissue (termed 'tumor-naive')." Dkt. 326 at 3; Tr. 283:10-13, 287:3-9 (Odegaard).

On May 9, 2019, JAMA Oncology published the peer-reviewed Reinert article, using Natera's tumor-informed assay Signatera and setting forth performance metrics. TX-4. The Reinert paper stated that "Circulating tumor DNA (ctDNA) has emerged as a promising non-invasive

biomarker for longitudinal assessment of a tumor throughout disease management." *Id.* at 2.

Trial showed that on November 20, 2020, Guardant presented a "New Product Introduction" document to reviewers for Medicare coverage approval. TX-585; Tr. 384:2-386:7 (Odegaard).

Performance Parameter	Signatera (Reinert et al)	Guardant (Parikh, et al)
Landmark sensitivity *Single post-treatment timepoint*	50% *(7/14)*	56% *(15/27)*
Surveillance sensitivity *Collected within ~4mo intervals*	88% *(14/16)*	91% *(20/22)*
Specificity *# ctDNA-/# recurrence free*	98% *(58/59)*	100% *(37/37)*
PPV *# recurred/# ctDNA+*	93% *(14/15)*	100% *(20/20)*
Lead time	8.7mo	6.9mo
CEA Sensitivity / Specificity	69% / 64% *(surveillance)*	35% / 81% *(landmark)*

GH CRC MRD Test meets the LCD Requirements:
- Identifies recurrence prior to radiographic recurrence
- Sensitivity/Specificity better than CEA
- Performance similar to Signatera

DENTIAL

GUARDANT

Here, Guardant presented a comparison of results from Reinert study with interim Parikh results. TX-585 at 7. Guardant's comparison included: "Performance similar to Signatera." *Id.*

When shown the Reinert/Parikh comparison Guardant's witness agreed that he did not see anything "false and misleading" in the comparison. Tr. 385:21-23 (Odegaard) ("Not at all."). The trial testimony was clear that the comparison of performance metrics from the two studies was fair:

> Q. At that time, you and Guardant thought it was [a] fair comparison to make?
> A. Correct.
> Q. And you still believe that today; right? You and Guardant believe this is a fair comparison to make today; right?
> A. It is.

Tr. 386:2-7 (Odegaard). The witness confirmed it was "totally fine" with a "side-by-side" comparison above. Tr. 385:18 (Odegaard). Guardant included these same comparisons in its formal application for Medicare reimbursement submitted in December 2020. TX-89 at 25. Guardant also made similar comparisons between Parikh and Reinert internally, as its witness Kristin Price conceded. Tr. 465:12-466-1 (Price) ("we definitely compared Signatera to Guardant Reveal in internal documents, for sure."); TX-729 at 19 (comparing: landmark sensitivity, surveillance sensitivity, landmark PPV, surveillance PPV, specificity, and CEA sensitivity/specificity).

On April 29, 2021, Clinical Cancer Research published the Parikh paper. TX-1. The paper provided "[d]etection of persistent circulating tumor DNA (ctDNA) after curative-intent surgery can identify patients with minimal residual disease (MRD) who will ultimately recur." *Id.* at 1.

The Parikh paper specifically invited comparison to the performance metrics of the prior Reinert paper. TX-1 at 2 ("To date, most ctDNA assays designed for MRD detection rely on initial genomic profiling of tumor tissue to identify tumor-derived alterations specific for each individual patient, so that these precise alterations can be evaluated in ctDNA" citing to note 6, the Reinert study) and 6 ("In summary, we show that plasma-only, tumor uniformed ctDNA-based detection of MRD is feasible and can produce ***comparable*** sensitivity and specificity to previously reported tumor informed approaches.") (emphasis added). The Parikh paper called out specific comparisons to Reinert: "Based on the methods employed by Reinert and colleagues (6), we assessed performance in patients with evaluable 'surveillance' draws, defined as a draw obtained within 4 months of clinical recurrence, and observed that sensitivity improved to 91%." *Id.* at 4.

In May 2021, Natera prepared a White Paper, a 7-page technical document explaining the technical difference between tumor-informed and plasma-only (tumor-naïve) approaches to ctDNA testing for MRD. TX-120; Tr. 563:16-564:13 (Masukawa). Like the peer-reviewed papers, the White Paper provided a background to the emerging technology: "Circulating tumor DNA (ctDNA) has emerged as a dynamic biomarker for the assessment of MRD and risk of recurrence in real time." TX-120 at 1. The White Paper includes with over thirty endnotes, primarily peer-reviewed papers in the field. *Id.* at 7. The White Paper includes extensive explanation of different approaches to MRD, "Tumor-informed strategy" and "Tumor-naïve strategy." *Id.* at 1-2. The White Paper includes an explanation of "Key requirements for a ctDNA assay suitable for MRD detection" – none of which is accused of being false and misleading. On one single page of the White Paper, it set forth the accurate data from the Reinert and Parikh papers both referenced by endnote. *Id.* at 3. With the White Paper, Natera also prepared a grid (TX-126) with accurate comparison data and footnotes to sources, including the Parikh and Reinert studies. Natera also prepared "Evidence Review" slides. TX-365.

On May 27, 2021, Guardant filed a complaint against Natera alleging false advertising

pursuant to the Lanham Act, California's unfair competition statute, and California common law. Dkt. 1. Guardant pointed to the White Paper in its complaint and made claims about Natera's advertising including Natera's statements in its White Paper that tumor naïve tests are unable to filter out background noise from CHIP mutations, which impacts specificity. Dkt. 1 ¶¶ 30-32.

At trial, many of Guardant's allegations have fallen away, including any allegation regarding Reveal's lack of CHIP filter and liability related to submissions to MolDX. Dkt. 509 at 7 ("[T]he Court finds that the MolDX-related communications do not fall under the scope of the [Lanham] Act."). Nor did Guardant pursue allegations regarding investor presentations as discussed in the summary judgment order. Dkt. 326.

Guardant's trial claim is the "apples-to-oranges" allegation—that Natera is liable for comparing the results of two peer-reviewed studies. Guardant points to two packages of information: (1) a Dear Doctor email (TX-220) with attached slides (TX-365 "Evidence Review"), Tr. 547 (Masukawa) and (2) a FedEx package including the seven-page White Paper (TX-120) and performance grid (TX-126). Tr. 573 (Masukawa describing contents of FedEx packets). Within those bodies of material, what Guardant points to are side-by-side comparisons on page 6 of the Evidence Review (TX-365) (Tr. 547 (Masukawa)); and page 3 of the White Paper (TX-120); and the performance grid (TX-126) included in the FedEx package. Guardant showed the grid to its witnesses Eltoukhy (Tr. 773) and Odegaard (Tr. 295). Guardant's survey expert showed only part of the side-by-side. Tr. 822-23 (Sowers) (stimulus derived from TX-369 Dear Doctor email with two metrics from Reinert and Parikh). The comparison of peer-reviewed data is the basis for Guardant's "apples-to-oranges" theory for alleged liability. Tr. 209:19-20; 201:10-12; 217:10 (opening); Tr. 567:8-567:9; 579:6-8 (Masukawa); Tr. 309:7-9; 21-23 (Odegaard); Tr. 406:24-407:1 (Price Direct); Tr. 1249:20-23 (Heitjan)

LEGAL STANDARD

Judgment as a matter of law is appropriate "[i]f a party has been fully heard on an issue during a jury trial and the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue[.]" Fed. R. Civ. P. 50(a). In making this determination, "the court should review all of the evidence in the record[.]" *Reeves v. Sanderson*

Plumbing Prods., Inc., 530 U.S. 133, 150 (2000). Rule 50 "allows the trial court to remove cases or issues from the jury's consideration when the facts are sufficiently clear that the law requires a particular result." *Weisgram v. Marley Co*., 528 U.S. 440, 448 (2000) (internal marks and citation omitted). Since the standard for granting judgment as a matter of law mirrors the standard for granting summary judgment, "the inquiry under each is the same." *Anderson v. Liberty Lobby, Inc*., 477 U.S. 242, 251 (1986). "A motion for judgment as a matter of law may be made at any time before the case is submitted to the jury." Fed. R. Civ. P. 50(a)(2).

ARGUMENT

I. NATERA IS ENTITLED TO JUDGMENT ON GUARDANT'S LANHAM ACT CLAIM (COUNT I)

To show false advertising under the Lanham Act, Guardant must show: "(1) a false statement of fact by the defendant in a commercial advertisement about its own or another's product; (2) the statement actually deceived or has the tendency to deceive a substantial segment of its audience; (3) the deception is material, in that it is likely to influence the purchasing decision; (4) the defendant caused its false statement to enter interstate commerce; and (5) the plaintiff has been or is likely to be injured as a result of the false statement, either by direct diversion of sales from itself to defendant or by a lessening of the goodwill associated with its products." *Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1139 (9th Cir. 1997). No reasonable jury could find for Guardant with respect to its claim for false advertising under § 43(a) of the Lanham Act. Guardant has a failure of proof for each of elements (1), (2), (3) and (5).

A. No Reasonable Jury Court Find The Accused Statements False Or Misleading

1. Accused Comparisons Set Forth Matters Of Opinion Not Objective Fact

To be actionable, a statement must be "a specific and measurable claim, capable of being proved false or of being reasonably interpreted as a statement of objective fact." *Coastal Abstract Serv., Inc. v. First Am. Title Ins. Co.*, 173 F.3d 725, 731 (9th Cir. 1999); *Ariix, LLC v. Nutrisearch Corp.*, 985 F.3d 1107, 1121 (9th Cir. 2021) ("[T]o be liable for false advertising under the Lanham Act, [the accused publication] must include false or misleading representations of fact, not simply statements of opinion."). The accused comparisons are not actionable; they are opinions.

Guardant's entire trial evidence and presentation is the "apples-to-oranges" allegation that the results of two peer-reviewed studies directed at MRD detection cannot be compared side-by-side. Tr. 208:17-209:2 (opening); Tr. 309:21-310:9 (Odegaard). Guardant's survey expert focused on the "comparison" of two metrics in side-by-side data. Tr. 812-13, 818-19 (Sowers). Even with respect to individual metrics that Guardant has accused from Natera's advertisements —e,g, hazard ratio, lead time, etc.—the accusation is the ***comparison*** itself is false or misleading. Tr. 209:24-210:09 (opening); Tr. 548:14-24 (Masukawa). Natera is not accused of publishing a false number from the Parikh study. Dkt. 326 at 13.

Whether the studies or individual metrics therein can be compared is ***not*** a verifiable objective fact. It is opinion. There is no test that determines whether it was wrong or right to compare the study results. There is no scientific test or consensus that one test is "apples" and the other, "oranges." At best it is a matter of scientific discussion, and one on which participants in the field disagree. Andersen Dep. Tr. 118:12-119:2 (agreeing they can be compared); Tr. 384:20-23, 385:17-23 (Odegaard). The Reinert study sets forth a set of performance metrics. TX-4. The Parikh study likewise sets forth its own set of performance metrics and acknowledges that it was designed to model the Reinert study. TX-1. Whether and to what extent the studies can be compared is a scientific opinion. *ONY*, 720 F.3d at 497 (dismissing Lanham Act claims concerning peer-reviewed data and holding that "while statements about contested and contestable scientific hypotheses constitute assertions about the world that are in principle matters of verifiable 'fact,' for purposes of the First Amendment and the laws relating to fair competition and defamation, they are more closely akin to matters of opinion, and are so understood by the relevant scientific communities"). As such, no reasonable jury could find liability that the accused statements are false or misleading. *Ariix*, 985 F.3d at 1121-22 (rejecting liability for claims based on comparative product ratings because it was opinion not verifiable fact); *Coastal*, 173 F.3d at 731 (reversing liability as the accused "statement was not a specific and measurable claim, capable of being proved false or of being reasonably interpreted as a statement of objective fact.").

2. No Reasonable Jury Could Find Accused Statements Literally False

Even if the accused comparisons presented an issue of fact, no reasonable jury could find

Natera's accused statements to be literally false. To show this, Guardant must establish that Natera's accused statement is false "on its face." *Southland Sod*, 108 F.3d at 1139. But the data in the accused statements was accurate. Tr. 1282:9-11 (Heitjan conceding accuracy). There is no false statement on the face of the advertisements.

(a) No Reasonable Jury Could Find Natera's Accused Statements Comparing Data To Be False By Necessary Implication

Guardant's theory for literal falsity relies on the doctrine of false by necessary implication, for which, "[a] statement is literally false by necessary implication when it does not explicitly state something that is untrue, but considering the advertisement in its entirety, the only reasonable interpretation of the statement is that it is untrue." Dkt. 759 at Inst. 31.

First, Guardant has unquestionably failed its burden of proof. Guardant's expert Dr. Hetjian addressed only TX-126 (comparison grid) but did not address the White Paper (TX-120) that was sent with the grid, or the Evidence Review (TX-365). The vague and conclusory statements he offered that "[t]here are emails to doctors, and things like that, that make the same types of comparisons," and for which his opinion on their statistical validity is the "[s]ame opinion[,] [t]hey're invalid," is a gross failure of proof. 1255:21-22, 1256:3 (Heitjan). The point of false advertising law is the effect of the advertisement on the intended consumer; that is why the statements have to be reviewed in their entirety, which Guardant's expert witness failed to do.

Second, there are many reasonable interpretations of the side-by-side table as Guardant's own evidence has shown. There is no one single interpretation of the scientific data, especially where—as here—all comparisons are presented to the consuming public (oncologists) with context including citations to the peer-reviewed studies and descriptions of their differences and limitations. TX-365, TX-120, TX-126; *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharms. Co.*, 290 F.3d 578, 587 (3d Cir. 2002) ("only an unambiguous message can be literally false."). To the extent that Guardant argues the one single message is that Natera's product is "superior"—that is vague and non-verifiable, exactly the sort of puffery and opinion that courts have repeatedly rejected. *Ariix*, 985 F.3d at 1121; *Coastal*, 173 F.3d at 731.

Third, trial evidence has shown the studies ***are*** comparable. The Parikh paper (with

Guardant co-authors) itself invites on its face comparison to Reinert. TX-1 at 2 ("Longitudinal timepoints were… based on the methods employed by Reinert and colleagues."). Importantly, Guardant itself offered a side-by-side comparison of the Reinert and Parikh data when it applied for Medicare coverage. TX-585; TX-89. Guardant's own witness conceded at trial (Odegaard)that the studies were comparable. It is "[n]ot at all" misleading to "compar[e] sensitivity, specificity, lead times, and PPV, all side by side between the two studies." Tr. 385:17-386:23. Guardant's own internal documents show that it compared the Parikh results to Reinert. TX-641; Tr. 785:7-10 (Eltoukhy); TX-729; Tr. 465:22-466:1 (Price) ("We definitely compared Signatera to Guardant Reveal in internal documents.").

The fact that Guardant internally and for Medicare review did a side-by-side of the Parikh and Reinert studies establishes as a matter of law that Guardant's "apples-to-oranges" theory must fail. As the Court held, the instructions provide for liability only if "non comparable things" are compared. Because Guardant itself compared the results shows that the studies are comparable. The test for literal falsity is objective. Here the objective evidence shows that Guardant compared the results of the Parikh and Reinert studies for its own purposes.

(b) No Reasonable Jury Could Find The Accused Statements Misleading

Putting aside literal falsity, no reasonable jury could find that the Natera statements were "misleading." An accused statement is "misleading" even if literally true "if it can be shown that the advertisement has misled, confused, or deceived the consuming public." *Southland Sod*, 108 F.3d at 1140. And Guardant must prove that the advertisements deceived a "substantial segment of consumers." Guardant's evidence was insufficient as a matter of law. There is no dispute that the consuming public here are highly educated oncologists who often receive educational materials from companies in the field. Tr. 853:13-15 (Sowers); Tr. 1267:1-6 (Heitjan). Not one oncologist took the stand or presented evidence that they were misled or deceived in any way by Natera's accurate side-by-side comparisons.

Guardant cannot point to the testimony of its expert, Dr. Heitjan, to show deception because he is not an oncologist, nor a medical doctor, nor does he have a biology or chemistry degree. . Tr. 1265:7-13. He conceded he did not speak to any doctors or oncologists and admitted he would not

know the effect on others of the advertisements and that he offered no opinion on that. Tr. 1267:10-15, 1268:17-20. In sum, Heitjan offered no opinion on the effect of the statements on the intended audience and was unqualified to do so.

As for Guardant's survey, it is insufficient to prove deception as a matter of law. The survey itself (TX-314) failed to account for the pre-existing knowledge of the respondents. All the Sowers survey did was present two metrics to the doctors about the messages communicated in the email. Tr. 847:4-847:9, 825:2-825:7 (Sowers). Notably, the bottom line from the Sowers survey based on just two sensitivity metrics from the Dear Doctor email is that "76.6 percent of respondents indicated that the email communicates that Signatera is somehow superior to Guardant." Tr. 829:25-830:2 (Sowers); Tr. 839:6-9 ("So the vast majority, 69.7 percent of oncologists and cancer surgeons understood the main message of Natera's email advertisement to be that Signatera is superior to Guardant's Reveal."). This conclusion on the general superiority of one product over the other does not support an allegation that Natera misled the consumers at issue. Sowers asked the wrong question. And even if Sowers had tried to ask the correct question, he failed to replicate market conditions (Tr. 853-55 (Sowers)) thus negating the results of the survey.

Finally, there is no evidence of causation to support a finding of deception. There is no dispute that publications like the Evidence Review (TX-365) and White Paper (TX-120) contain copious technical information and that MRD is an emerging field. Sowers conceded he did not test any of that other material. Tr. 844-58 (Sowers). Although oncologists in the market can freely Google and read the Parikh and Reinert studies, Sowers' survey instructed them not to do so. *Id.* This undermines any result that Sowers obtained. There must be a link between what Natera actually did and any consumer confusion or deception. *Simpson Strong-Tie Co. Inc. v. MiTek Inc.*, 2023 WL 8697700, at *17 (N.D. Cal. Dec. 15, 2023) (failure to show that false statements actually deceived or had tendency to deceive substantial segment of relevant audience). This link is entirely missing from all of Guardant's trial evidence.

(c) No Reasonable Juror Could Find Natera's Comparison Of Individual Metrics To Be False Or Misleading.

As well as an overall "apples to oranges" theory as to the comparisons, Guardant through its

expert Heitjan sought to compare individual metrics in the grid (TX-126) to try to establish liability for failure rate; presurgical sensitivity; longitudinal sensitivity; hazard ratio; PPV; NPV; and diagnostic lead time. Guardant's "proof" fails as a matter of law for each metric. Importantly, as stated above, Heitjan only addressed TX-126 and offered no opinion on the different statements, *i.e*, the White Paper (TX-120) and the Evidence Review (TX-365). That is a failure of proof as to those publications. Next, this element requires the metrics mislead its intended audience, oncologists. Heitjan spoke to no doctors or oncologists, and is not one himself. Tr. 1267:17-20. Indeed, plucking individual metrics out of an advertisement (and not the other technical material that accompanied the comparisons) is the incorrect analysis. The advertisements must be evaluated in their entirety. Dkt. 759 at p. 35.

B. No Reasonable Jury Could Find The Alleged False Advertising Was Material In That It Was Likely To Influence The Purchasing Decision

Guardant failed to put in any evidence to meet this element, which requires that the "deception is material, in that is likely to influence the purchasing decision[.]" *Southland*, 108 F.3d at 1139. Guardant's survey expert, Mr. Sowers, conceded his survey did not address the issue of the likelihood of influencing purchasing decisions. Tr. 850 (Sowers) (agreeing that his survey "didn't ask the people who responded to your survey whether they made any purchasing decisions based on the Natera email; right?"). And expert Dr. Heitjan also conceded he offered no opinion on any purchasing decisions as a result of the comparisons. Tr. 1268:17-20 ("Q. So, Dr. Heitjan, you really don't know anything about any purchasing or ordering decisions when it comes to Signatera and Reveal; right? Fair? A. Yeah, I don't know about that."). There was no evidence that the side-by-side tables presented amongst copious other technical information, and understood in light of the education and knowledge of oncologists, influenced any purchasing decision. There was a failure of proof for this element.

C. No Reasonable Jury Could Find That Guardant Was Or Is Likely To Be Injured As A Result Of The False Or Misleading Statement

Liability requires proof of economic harm and damages ***as a result of*** the alleged accused false comparisons. *Southland Sod*, 108, F.3d at 1139. All Guardant's theories suffer the fatal flaw of not being causally connected to the accused conduct. Guardant's CEO admitted he never

disclosed in any earnings call that anything Natera did harmed Guardant. Tr. 757:19-757:22 (Eltoukhy). Guardant's damages theory was the alternative of (1) disgorgement of $95 million reflecting the entirety of Signatera's U.S. profits from February 2021 through August 2023 in CRC clinical market minus cost of goods sold ***or*** (2) corrective advertising of $74 million reflecting the cost of Natera's actual advertising expenditures (TX-98) multiplied by three. Both numbers are inflated and unreliable, and there is insufficient basis for a reasonable jury to find either of them.

As for disgorgement, Guardant damages expert, Mr. Malackowski, testified his analysis and resulting calculations were the result of applying an erroneous legal standard: he testified it was a "penalty" for Natera's conduct. Tr. 1342:2-5. But Lanham Act damages are compensatory only. 15 U.S.C.A. § 1117(a) ("Such sum . . . shall constitute compensation and not a penalty."). Malackowski confirmed his disgorgement theory was a "penalty" because he testified he was not opining that the sales (or at least some unknown portion) would have been made regardless of the advertisements. Tr. 1341:23-13:425; 1342:15-23. In other words, Malackowski freely admitted that the transfer of profits was a windfall to Guardant as penalty to Natera.

Malackowski therefore wrongly attributes ***all of*** Natera's U.S. Signatera clinical sales during his disgorgement period to the false advertisements instead of only those portions linked to the liable conduct. Malackowski conceded his disgorgement damages opinion fails to account for many reasons that doctors purchase Signatera unrelated to the advertisements, including Signatera's first-mover advantage, doctors' preference for Signatera over Reveal for technical reasons such being tumor informed (Tr. 1333:12-22) having more robust data supporting Signatera (Tr. 1335:25-1336:13), and its ability to provide quantification—a feature Reveal lacks and which is a "purchase driver. Tr. 1334:8-12. Not only that, Malackowski could not identify a single Guardant lost sale or lost customer as a result of Natera's statements. Tr. 1368:3-13.

With respect to corrective advertising, Guardant has failed to prove that ***prospective*** corrective advertising is a proper form of actual damages. The version of Reveal that was the subject of Natera's allegedly false ads, 1.2, was no longer on the market as of mid-summer 2023; thus there are no false impressions to "correct." Tr. 361:17-23. Moreover, Guardant's theory is entirely speculative. Malackowski conceded that Guardant was a well-established market leader and had

strong connections with oncologists. Tr. 1311:12-15. In 2019-2021, Natera was the new entrant. Tr. 1367:21-24. The first flaw is assuming the well-known market leader in oncology tests would spend the same in marketing as the new entrant to correct the impression made by the new entrant. The second flaw is applying an arbitrary three times multiplier to the expenditures the newcomer actually spent to correct the misimpressions of the well-known market participant. Malackowski had no experience or expertise to apply such a multiplier. Tr. 1329:12-21. Again this is akin to a "penalty" on Natera, which is inconsistent with the Lanham Act. Finally, the corrective advertising damages are speculative because despite claiming it was harmed by the advertisements being disseminated during the critical launch period—first half of 2021—Guardant has not actually spent any money on corrective advertising to date.

II. FIRST AMENDMENT PRINCIPLES PRECLUDE LIABILITY

Natera's Thirteenth Affirmative Defense asserted that its activities were protected under the First Amendment. Dkt. 48 (Natera's Thirteenth Affirmative Defense). Natera raised this issue in the parties' June 8, 2023 Joint Pretrial Statement. Dkt. 362 at 20-21 (identifying as disputed issue 5.b. "Whether Natera's advertising constitutes a commercial advertisement or promotion" and setting forth that "[th]e meaning of 'commercial speech' in the context of the Lanham Act tracks the doctrine of 'commercial speech' in the First Amendment context," citing *Bolger v. Youngs Drug Prod. Corp.*, 463 U.S. 60, 66 (1983)). In the March 19, 2024 Pretrial Conference Order, this Court listed a disputed issue being "[w]hether Natera's advertising constituted a commercial advertisement or promotion." Dkt. 501 at 5, item B.3. "[F]ree speech principles inform [the Court's] application of the Lanham Act." *ONY*, 720 F.3d at 497. The trial evidence has shown the Guardant's theory for liability is precluded under two separate First Amendment doctrines.

A. *ONY* Applies To Preclude Lanham Act And State Law Claims Based On Peer-Reviewed Data

This Court has ruled that the Second Circuit's decision in *ONY v. Cornerstone* applies in this case. Dkt. 610 at 18. In *ONY*, the parties were competitors that sold neonatal surfactants to treat infants' lungs. 720 F.3d at 492-93. The defendant co-authored a peer-reviewed paper, and then sent out promotional materials touting the results. *Id*. at 493-94. Plaintiff sued for Lanham Act and

state law false advertising claims. *Id*. at 495 The Second Circuit dismissed the claims because they depended on the presentation of peer-reviewed scientific data, *id.* at 498-99, and this Court should do the same for Guardant's claims.

The touchstone of *ONY*'s analysis—directly applicable to Guardant's claims—was that verifiable factual assertions may lead to liability, but opinions do not. *ONY* emphasized that the line between verifiable fact and opinion "is not always a clear one." 720 F.3d at 496. The Second Circuit recognized that scientific "assertions" may be "verifiable fact," for purposes of the First Amendment and the laws relating to fair competition and defamation, they are more closely akin to matters of opinion" and thus not actionable. *Id*. at 497. *ONY* explained that disagreements about the results of peer-reviewed science are better resolved with vigorous debate rather than in the courts. 720 F.3d at 497-97 ("[C]ourts are ill-equipped to undertake to referee such controversies. Instead, the trial of ideas plays out in the pages of peer-reviewed journals, and the scientific public sits as the jury."). This analysis led *ONY* to dismiss the false advertising claims based on published data. *Id*. (citing *Underwager v. Salter*, 22 F.3d 730, 736 (7th Cir. 1994) ("Scientific controversies must be settled by the methods of science rather than the methods of litigation").

Thus, *ONY* concluded that "statements about contested and contestable scientific hypotheses … are more closely akin to matters of opinion [than statements of fact], and are so understood by the relevant scientific communities." *Id.* at 497. As such, the Court ruled that conclusions drawn from such publications could not be grounds for Lanham Act liability.

The *ONY* conclusion applies with even more force in this case. *ONY* included a single peer review paper with promotional material. Here, the Court has previously found that "all of Natera's advertising statements at issue are directly derived from the Reinert study and the Parikh study. The "numbers are not literally false on their face." Dkt. 326 at 13. Natera is accused of comparing side-by-side the results directly derived from those two studies in an "emerging" medical area that is of undisputed medical importance: MRD analysis to detect the recurrence of CRC. But the Parikh paper expressly invited comparison with the results of the Reinert paper. This is precisely the "matter of argument" or scientific debate—two separate studies in the same area—that *ONY* warned should not be subject to Lanham Act and related state law liability. Indeed, third-party witness Dr.

Claus Andersen testified by deposition that his Reinert study generated "a lot of interest" and was published in a "world-renowned journal" and that his and the Parikh study have generated scientific debate, including his own letter to the editor related to the Parikh study. Andersen Dep. Tr. 74:07-74:16; 98:14-98:23. Such scientific debate related to peer-reviewed data is what *ONY* intended to exclude from the Lanham Act to prevent what Guardant is seeking here: a courtroom judgment that chills speech instead of open scientific debate.

Guardant alleges that Natera committed false advertising by setting forth the results of two peer-reviewed studies, one on tumor informed (Reinert) and the other one tumor naïve (Parikh). *ONY* teaches that such comparisons cannot be the basis for liability.

B. Natera's White Paper And Related Publications Are Protected Speech Because Accused Portions Are "Inextricably Intertwined" With Fully Protected Speech

Separate from *ONY*, First Amendment principles preclude liability for the technical submissions that Natera provided to doctors. Providing side-by-side comparisons of peer reviewed data—especially when in the context of a larger publication—is protected speech.

As this Court knows, the liability under the Lanham Act requires a review of the accused statement "in its full context." *Southland Sod*, 108 F.3d at 1139. Similarly, First Amendment precedent requires that "courts must determine as a threshold matter if a publication as a whole constitutes commercial speech." *Dex Media*, 696 F.3d at 952. If the publication "does no more than propose a commercial transaction," then the Court must turn to the "factors identified in *Bolger* includ[ing] 'three characteristics which, in combination support[]' a conclusion that the document 'at issue constitute[s] commercial speech, including (i) their advertising format, (ii) their reference to a specific product, and (iii) the underlying economic motive of the speaker.'" *Dex Media*, 696 F.3d at 958 (quoting *Assoc. of Nat'l Advertisers v. Lungren*, 44 F.3d 726, 728 (9th Cir. 1994)) (citing *Bolger v. Youngs Drug Prod. Corp.*, 463 U.S. 60 (1983)). Here, the White Paper (TX-120) and Evidence Review (TX-365) are not traditional offers for sale. However, even if the threshold analysis characterizes the overall publication as commercial, the next step is to determine whether it includes both protected and commercial speech—the "inextricably intertwined" test. *Dex Media*, 696 F.3d at 959.

"When commercial speech is 'inextricably intertwined with otherwise fully protected speech,' it would be 'artificial and impractical' to apply different levels of scrutiny to the different speech components." *Dex-Media*, 696 F.3d at 961 (quoting *Riley v. Nat'l. Fed'n. of the Blind*, 487 U.S. 781, 796 (1988)); *Gaudiya Vaishnava Soc. V. City and Cnty. Of San Francisco*, 952 F.2d 1059, 1066 (9th Cir. 1990) *as amended on denial of reh'g* (Dec. 26, 1991) (affording full First Amendment protection to the sale of merchandise with religious, political, philosophical, or ideological message because commercial speech is in "inextricably intertwined" with otherwise protected speech).

In *Dex-Media*, the Ninth Circuit found that the Yellow Pages (a commercial enterprise) contained both advertisements, commercial speech ***and*** protected speech. 696 F.3d at 965 ("To be sure, the Yellow Pages Companies are in the business of selling advertisements and contracted to distribute the noncommercial speech to make their advertising space more desirable due to greater directory use."). Because the protected speech was "inextricably intertwined," the Ninth Circuit gave the Yellow Pages full protection. The same analysis applies here.

For instance, the White Paper (TX-120) includes copious material unrelated to the charges of false advertising in this case. The endnotes reflect a bibliography of peer-reviewed material in the "emerging" field of testing for circulating tumor DNA (ctDNA) as a biomarker to assess the risk of recurrence of colorectal cancer, a major health issue in the United States. There is no challenge to the accuracy of the endnotes or the copious technical and educational information in the White Paper. Guardant's allegations focus on only one section of the White Paper, which contains a side-by-side comparison of peer-reviewed data, and the comparison grid that was circulated to oncologists in the same FedEx packet as the White Paper. TX-126; Tr. 573 (Masukawa). It is all part of the same publication. And critically, Guardant's own witness conceded that publications like the White Paper "are educational material" for doctors. Tr. 296-97 (Odegaard).

The side-by-side comparison of data from Parikh (tumor naïve) and Reinert (tumor informed) is "inextricably intertwined" with the protected speech in the White Paper. The White Paper describes in detail the different approaches to MRD testing for CRC. TX-120. It explains exactly how tumor-informed testing works. TX-120. It provides important context for Natera's side-by-side grids by explaining the differences in the patient cohorts between the peer-reviewed

studies and how that may implicate the reported results. TX-120 at -769 ("Because the published data were not stratified by stage II/III, there is an unknown contribution of MRD detection from the stage IV patients, thus confounding performance analysis because the allele fraction of ctDNA is higher in metastatic patients."). And the endnotes provide academic references for Parikh, Reinert, and multiple other publications in the field. Both Guardant and Natera witnesses have consistently testified that both parties' advertising provides references to the underlying studies and data on which the statements are based, that this is a common industry practice, and that oncologists obtain and review those studies in assessing any claims made in advertising material. Tr. 1079:4-6 (Chapman); Tr. 650:5-8 (Masukawa); Tr. 853:16-20 (Sowers).

Further, not only does Natera speak here on a matter of public concern, but Guardant is also a limited-purpose public figure in this context. *Makaeff v. Trump Univ., LLC*, 715 F.3d 254, 270 (9th Cir. 2013) ("Trump University is a limited public figure because a public debate existed regarding its aggressively advertised educational practices.").

Because Natera's accused publications are fully protected speech, it was incumbent on Guardant to establish by clear and convincing evidence that Natera's challenged expression was factually false and uttered with actual malice relative to the truth—which Guardant has not done and cannot do. *Id.* (claims failing without proof of actual malice); *Exeltis USA Inc. v. First Databank, Inc.*, 520 F. Supp. 3d 1225, 1235 (N.D. Cal. 2021) (same). Guardant's failure to show actual malice defeats each of Guardant's claims (the Lanham Act (Count I); False Advertising in Violation of Cal. Bus. & Prof. Code §17500 Et Seq. (Count II); Unlawful Trade Practice in Violation of Cal. Bus. & Prof. Code §17200 (Count III); and Common Law Unfair Competition (Count IV)) because clear and convincing evidence of actual malice is required wherever a claim's "gravamen is the alleged injurious falsehood of a statement." *Id.*

Finally, to the extent the Court finds the issue of whether Natera's speech is fully protected close, the doctrine of constitutional avoidance requires finding that the Lanham Act is inapplicable in order to avoid serious First Amendment concerns. *Gallardo v. Lynch*, 818 F.3d 808, 818 (9th Cir. 2016).

III. NATERA IS ENTITLED TO JUDGMENT AS A MATTER OF LAW ON GUARDANT'S CLAIM UNDER CALIFORNIA COMMON LAW OF UNFAIR COMPETITION (COUNT IV)

There is no evidence from which a reasonable jury could find for Guardant on its claim for unfair competition pursuant to California common law. Guardant must prove that: (1) the plaintiff invested substantial time, skill or money in developing its property; (2) the defendant appropriated and used the property at little or no cost; (3) the plaintiff did not authorize or consent to the property's appropriation and use; and (4) the plaintiff was injured by the appropriation and use. *Dyson, Inc. v. Garry Vacuum, LLC*, No. 2010 WL 11595882, at *9-10 (C.D. Cal. July 19, 2010); Rest. (First) Torts § 711 (liability for common law unfair competition if defendant "fraudulently markets his goods or services as those of another."). Further, "[t]he tort [of unfair competition] developed as an equitable remedy against the wrongful exploitation of trade names and common law trademarks that were not otherwise entitled to legal protection." *Bank of the W. v. Superior Ct.*, 2 Cal. 4th 1254, 1263 (1992) (citations omitted). Caselaw formulations of what conduct constitutes common law unfair competition provide the legal framework for analyzing the evidence.

A. No Reasonable Jury Could Find Natera Committed Unfair Competition Under California Common Law

Guardant has failed to provide sufficient evidence to satisfy the elements. The evidence at trial is Natera's statements in which Natera compares the results of two peer-reviewed studies, Reinert and Parikh. TX-120; 126; 365. No Guardant witness has testified that Guardant "invested substantial time, skill or money in developing its property," that Natera "appropriated and used the property at little or no cost," that Guardant "did not authorize or consent to the property's appropriation and use," or that Guardant has been injured by "the appropriation and use." *City Sols., Inc. v. Clear Channel Commc'ns*, 365 F.3d at 842-43. Indeed, the essence of Guardant's claim is that Natera's advertisements ***distinguish*** Natera's Signatera from Guardant's Reveal. Dkt. 1 ¶ 78 (Natera's "marketing deceives potential customers about the nature, characteristics, and qualities of Signatera in comparison, connection, or association with Plaintiff's Reveal.").

B. California Common Law Today Is Limited To "Passing Off"

Separate and apart from Guardant's failure to meet the elements of California common law,

binding precedent sets forth that California common law is limited to "passing off," which Guardant has not attempted to prove. California courts are clear: "The common law tort of unfair competition is generally thought to be synonymous with the act of 'passing off' one's goods as those of another." *Bank of the W.*, 2 Cal. 4th at 1263. Not only do California courts recognize this rule of law, but the Ninth Circuit has likewise ruled the same. *Southland Sod,* 108 F.3d at 1147 ("Because Plaintiffs' allegations do not amount to 'passing off' or its equivalent, Defendants are correct that Plaintiffs' claim for unfair competition was properly dismissed."). There is no law to the contrary; indeed, *Southland Sod* is binding and relied upon by this Court in formulating the legal standard for Lanham Act liability.

Courts in the Ninth Circuit, including in this District, have consistently and repeatedly held that a plaintiff cannot state a claim for common law unfair competition where it does not allege that the defendant "passed off their goods as those of another" or "exploit[ed] trade names or trademarks[.]" *Sybersound Recs., Inc. v. UAV Corp.*, 517 F.3d 1137, 1153 (9th Cir. 2008) (dismissing California unfair competition common law claim for failure to state a claim). Courts have repeatedly dismissed unfair competition claims on this ground:

- *Amaretto Ranch Breedables, LLC v. Ozimals, Inc.*, 2011 WL 2690437, at *2 (N.D. Cal. July 8, 2011) ("[Plaintiff's] allegations do not concern [Defendant] passing off [Plaintiff's] goods as its own," and so Defendant's "Motion to Dismiss the common law unfair competition claim is GRANTED.");
- *Aevoe Corp. v. Pace*, 2012 WL 13069926, at *5 (N.D. Cal. Apr. 6, 2012) ("Defendant fails to plead a cause of action under California common law, for passing off one's good as those of another," and so the motion to dismiss Defendant's common law unfair competition claim is granted.) (internal quotations omitted);
- *Total Recall Techs. v. Luckey*, 2016 WL 199796, at *10 (N.D. Cal. Jan. 16, 2016) ("Total Recall has not alleged passing off as the basis for this claim… Accordingly, Total Recall's common law unfair competition claim is DISMISSED.");
- *Automated Pet Care Prods., LLC v. PurLife Brands, Inc.*, 703 F. Supp. 3d 1022, 1033 (N.D. Cal. 2023) (Plaintiff's "common law unfair competition claim (Count 4) fails

because… [t]he amended counterclaims do not allege that Whisker attempted to pass off its products as Smarty Pear's.");

- *Groupion, LLC v. Groupon, Inc.*, 859 F. Supp. 2d 1067, 1083 (N.D. Cal. 2012) ("[I]n California common law unfair competition claims are limited to cases in which a party passes off their goods as another. As discussed above, Groupion did not bring such a claim" and so there is no basis to award punitive damages.);
- *Sachs v. Indus. Indem. Ins. Co.*, 1993 WL 93562, at *3 n.1 (C.D. Cal. Jan. 15, 1993) ("Plaintiff has provided the Court with absolutely no evidence that damages for the common law tort of unfair competition have ever been held by California courts to be available for any behavior other than 'passing off.'").

There is no allegation or evidence of Natera passing off its goods as Guardant's. In fact, the evidence showed the opposite: that Natera distinguished its products from Guardant. As such, there can be no liability under California common law for unfair competition.

C. Even If Precedent Did Not Limit California Unfair Competition To "Passing Off," It Fails To Reach The Accused Conduct At Trial

In the limited circumstances where courts have considered whether a common law unfair competition claim can be broader than passing off, such analysis is either dicta or expressly limited to the ***misappropriation*** context. *Cel-Tech Commc'ns., Inc. v. Los Angeles Cellular Tel. Co.*, 20 Cal.4th 163, 193 (1999) (Judge Kennard concurring "Even though the tort has been extended to situations other than classic 'passing off,' deceptive conduct has remained at the heart of unfair competition."); *Ojala v. Bohlin*, 178 Cal.App.2d 292, 301 (1960) ("The scope of unfair competition may not be limited to a particular type of deception. The legal concept of unfair competition has evolved as a broad and flexible doctrine with a capacity for further growth to meet changing conditions, and there is no complete list of the activities that constitute unfair competition. It is self-evident that the misuse of confidential information in breach of trust and in competition with the trustor would be unfair competition. For that reason alone equity would grant appropriate relief"). Such cases do not save Guardant's common law unfair competition claim because Guardant has not shown misappropriation or other deceptive act. *See Dyson*, No. 2010 WL 11595882, at *9-10

(distinguishing *Cel-Tech* and *Ojala*).

While the Court previously ruled against Natera for the jury instructions (Dkt. 610 at 29), the Court may now resolve this issue in the context of a Rule 50(a) motion. And while the Court previously recognized that "there is some ambiguity in the substantive law," Natera respectfully submits that the authorities on which the Court relied for the jury instructions do not address whether Guardant has met its burden to prove the elements of common law unfair competition. *Acad. of Mot. Picture Arts & Scis. v. Creative House Promotions, Inc.*, 944 F.2d 1446, 1457 (9th Cir. 1991). (Dkt. 610 at 29) did not involve a claim for common law unfair competition; it addressed the substantial congruence between the Lanham Act and statutory unfair competition claims pursuant to Cal. Bus. & Prof. Code §§ 17200 *et seq*. (claims the Court has ordered will be addressed after trial in this case). *Seltzer v. Green Day, Inc*. 725 F.3d 1170, 1180 n.1 (9th Cir. 2013) and *Zeltiq Aesthetics, Inc. v. BTL Indus., Inc.*, 32 F. Supp. 3d 1088, 1099 (N.D. Cal. 2014) suffer from the same defect because they rely on *Cleary v. News Corp*., 30 F.3d 1255, 1262 (9th Cir. 1994) for the proposition that "[t]his Circuit has consistently held that state common law claims of unfair competition and actions pursuant to California Business and Professions Code § 17200 are 'substantially congruent' to claims made under the Lanham Act." But *Cleary v. News Corp.* cites to the *Academy of Motion Picture Arts & Sciences v. Creative House Promotions, Inc.* for this proposition and (as set out above), that case did not involve or discuss a claim for common law unfair competition. The California Supreme Court has made clear that "the statutory definition of unfair competition cannot be equated with the common law definition." *Bank of the W. v. Super. Ct.*, 833 P.2d 545, 551 (Cal. 1992) (quotation marks and citation omitted). For this reason, any alleged substantial congruence between common law unfair competition, statutory unfair competition, and the Lanham Act is illusory absent allegations akin to a claim for passing off (which Guardant has not alleged).

D. Under Guardant's Approach, California Common Law Of Unfair Competition Is Preempted By The Lanham Act.

Guardant's theory of California common law unfair competition leads directly to preemption and cannot be sustained. Under Guardant's theory, the elements of California common law are

"congruent" with the Lanham Act. Dkt. 261 at 10 n.6. However, California common law permits punitive damages. Cal. Civ. Code § 3294; *Duncan v. Stuetzle*, 76 F.3d 1480, 1490 (9th Cir. 1996). The effect of Guardant's position is an improper punitive "add on" to the Lanham Act. "Federal preemption occurs when: (1) Congress enacts a statute that explicitly preempts state law; (2) state law actually conflicts with federal law; or (3) federal law occupies a legislative field to such an extent that it is reasonable to conclude that Congress left no room for state regulation in that field." *Chae v. SLM Corp.*, 593 F.3d 936, 941 (9th Cir. 2010) (quotations omitted). State law that shares a "common end" with a federal law may nevertheless conflict when it is "at odds with achievement of the federal decision about the right degree of pressure to employ." *Crosby v. Natl. For.,* 530 U.S. 363, 370-80 (2000) (state law conflicted with Congress' "deliberate effort to steer a middle path."). Here, the Lanham Act expressly provides a careful damages framework and provides for "compensatory" but not punitive damages. 15 U.S.C.A. § 1117(a) ("Such sum . . . shall constitute compensation and not a penalty."). *Binder v. Disability Grp., Inc.*, 772 F. Supp. 2d 1172, 1183(C.D. Cal. 2011) ("Punitive damages are not available under the Lanham Act."). The Lanham Act strikes an intentional balance between fair competition and free speech. If the Lanham Act and common law claims are congruent while the common law provides excessive penalties, then there is conflict and preemption should ensue.

Finally, the First Amendment provides protection against state law tort liability on matters of public importance as in this case. *Snyder v. Phelps*, 562 U.S. 443, 458 (2011).

IV. NATERA IS ENTITLED TO JUDGMENT AS A MATTER OF LAW ON GUARDANT'S CLAIM FOR WILLFULNESS

To establish willfulness, Guardant must show that Natera "knew its advertising was false or misleading, or it acted with reckless disregard for, or willful blindness to, the false or misleading nature of its advertising." Dkt. 736 (Jury Instruction No. 52). No reasonable jury could make such a finding. Guardant has presented no evidence that Natera knew its advertising was false or misleading, or that Natera acted with reckless disregard for the truth. Natera witnesses have consistently testified to the contrary. Tr. 1075:1-15 (Chapman); Tx. 660:7-12 (Masukawa). Natera had a good faith belief that the material contained in its advertisements was accurate and

disseminated those claims to ensure patient safety. *Grasshopper House, LLC v. Clean & Sober Media LLC* 394 F. Supp. 3d 1073, 1110-1111 (C.D. Cal. 2019), *aff'd in part, vacated in part, remanded*, 2021 WL 3702243 (9th Cir. Aug. 20, 2021) (finding no willfulness, and on remand maintaining its denial of disgorgement profits and attorney fees).

V. NATERA IS ENTITLED TO JUDGMENT AS A MATTER OF LAW ON GUARDANT'S CLAIM FOR PUNITIVE DAMAGES

Under California law, punitive damages are only available when "clear and convincing evidence" shows that the defendant is "guilty of oppression, fraud, or malice." Cal. Civ. Code § 3294(a). Defendants must have consciously disregarded the truth (fraud) or the rights or safety of others (malice). Cal. Civ. § 3294(c)(1); *In re Volkswagen "Clean Diesel" Mktg.*, 2019 WL 693224, at *7 (N.D. Cal. Feb. 19, 2019) (fraudulently presenting its engines as low-emission and utilizing software to evade emissions testing); *Hardeman v. Monsanto Co.*, 997 F.3d 941, 971 (9th Cir. 2021) (consciously disregarding the carcinogenic health risks of Roundup). Aggressive competition without more are not grounds for punitive damages. *Sitco, Inc. v. Agco Corp.*, 2006 WL 908065, at *3 (D. Idaho Apr. 7, 2006) (punitive damages requires "an extremely harmful state of mind, described variously as with malice, oppression, fraud, gross negligence, wantonness, deliberately, or willfully"). Guardant has presented no evidence that Natera is "guilty of oppression, fraud, or malice." Indeed, Natera's witnesses testified that Natera was motivated by communicating the truth for patient safety. Tr. 1075:1-15 (Chapman). And Guardant's witnesses have confirmed that the metrics used by Natera were objectively true (and that Guardant itself made such comparisons between the Reinert and Parikh studies regularly). Without presenting any evidence of oppression, fraud or malice, Guardant's claim for punitive damages fails.

CONCLUSION

Natera respectfully requests this Court grant judgment as a matter of law for Natera on all of Guardant's claims.

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